



USER GUIDE



INNOVATING METAL-FREE IMPLANTOLOGY



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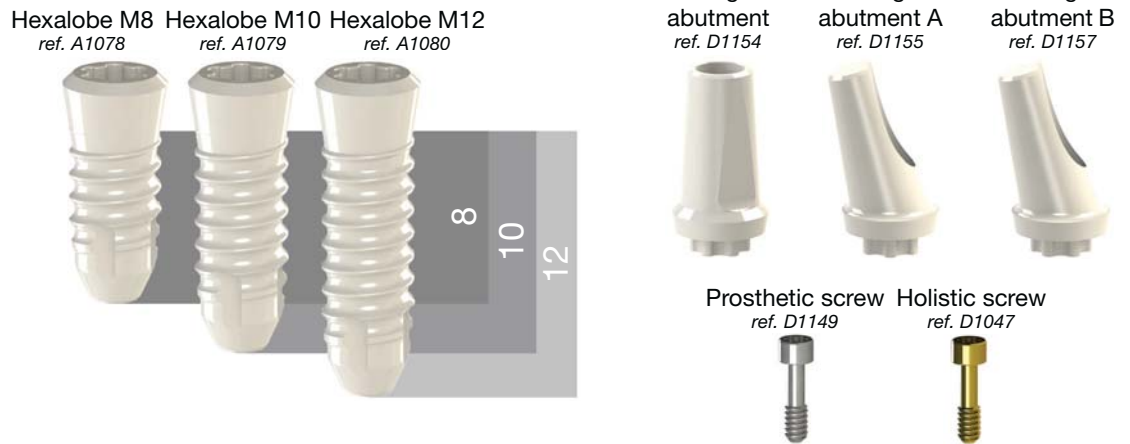


1. Implant System

AXIS provides a non-metallic dental implant system. AXIS implants are available in two different versions: a screwed two-piece and a one-piece implant.

AXIS Hexalobe Implants

This two-piece implant is composed of an HIP Y-TZP zirconia fixture, a high performance polymer abutment and a prosthetic or holistic-gold screw.



AXIS Monobloc Implants

This one-piece implant is made out of HIP Y-TZP zirconia.





2. Pre-operative Planning

A. Indications & Contra-indications

Indications

Note

The rule for choosing a dental implant is to use the one with the greatest diameter, with the resistance of that implant being proportional to the cube of its diameter.

AXIS implants are especially indicated to replace a single tooth (1 tooth - 1 implant).

Contra-indications

General Contra-indications

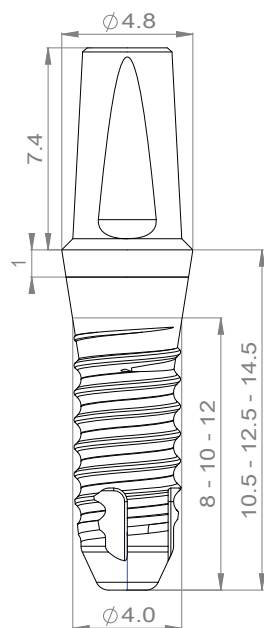
Contra-indication include, but are not limited to cardiovascular disease, uncontrolled diabetes, coagulation disorders (including taking anticoagulants), metabolic bone disease, chemotherapy or radiation treatment, chronic inflammation, metabolic or systemic disorders associated with lesions and/or bone healing, the use of pharmaceutical products that block or modify bone healing.

Absolute Contra-indications

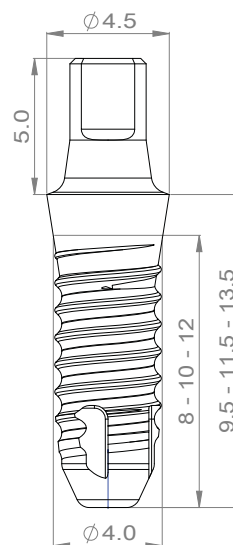
Contra-indication include, but are not limited to uncontrolled para-functional diseases (bruxism, clenching or grinding of teeth), insufficient bone length or width, insufficient inter-arc gap, intraoral infection, insufficient coverage of the soft tissue and disorders that impede the ability of patients to maintain adequate oral hygiene.

We may add other factors that can negatively influence success rates, such as smoking.

B. Dimensions of Implants & Abutments

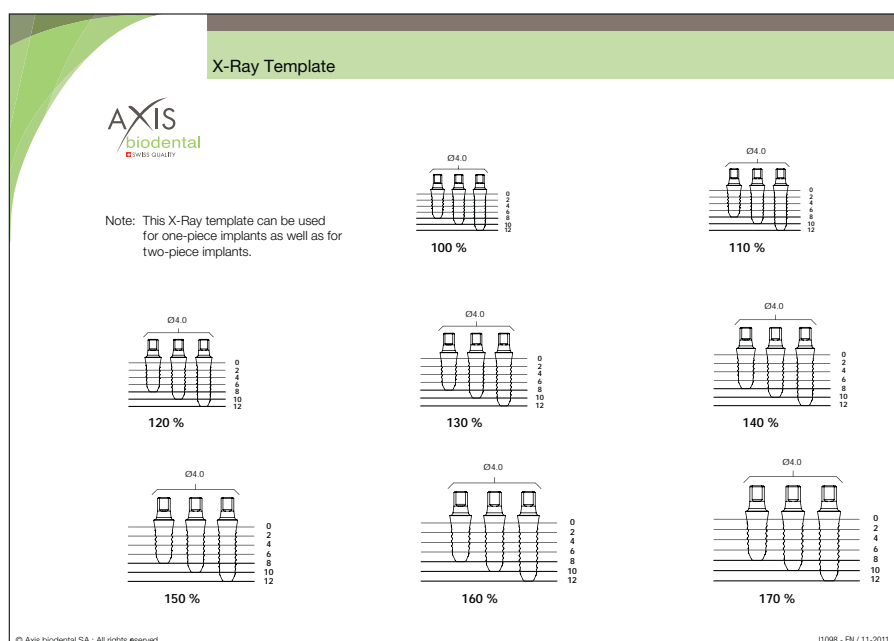


Note: Dimensions are in millimeters (mm).



C. X-ray Template

An X-ray template is available (ref. I1098). It allows you to select the adequate implant length.



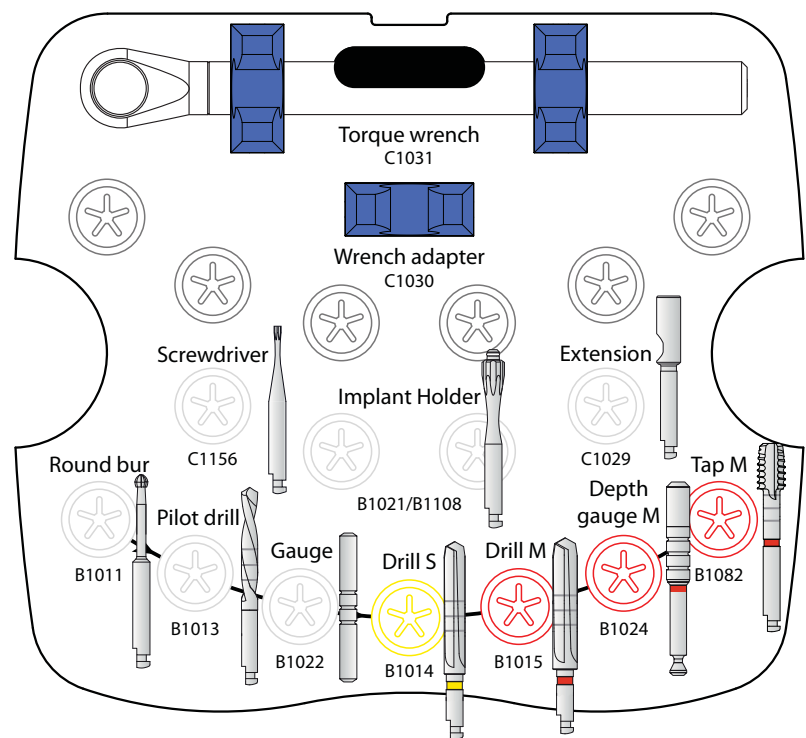
3. Hexalobe Implant's Operating Procedure



A. Surgical Procedure

i. Instruments Presentation

A sterilizable implantology kit (ref. B1085), containing all necessary instruments required to place AXIS implants is available.







Attention

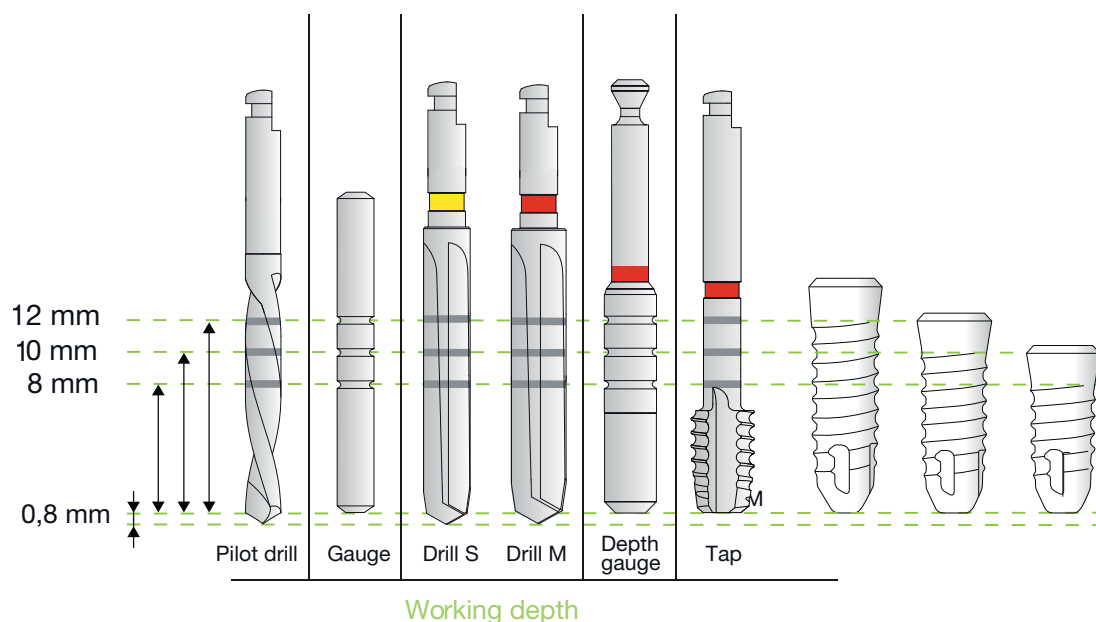
All instruments must be sterilized before use.

For sterilizing procedures, please refer to Section 6: *Cleaning - Sterilizing - Storage*.

In addition to the content of the surgical kit, other instruments are available.

Tissue punch (ref. B1010)	
Profile Drill (ref. B1170)	
Point drill (ref. B1012)	
Handpiece extension (ref. C1029)	

Three tick marks indicating the working depth (8, 10 and 12 mm) have been etched on the instruments required for realizing the implant site.



Important

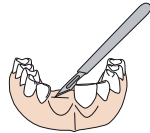
In order to create optimal conditions for the integration of the implant, it is imperative to **respect the recommended speeds** and to apply a **reasonable pressure** during the site preparation. The respect of these rules will prevent over-heating which could slow or prevent the osseointegration of the implant due to **bone necrosis**.

3. Hexalobe Implant's Operating Procedure

ii. Implant Site Preparation

Osseous Crest Access

Tissue punch (B1010)



For accessing the bone, it is possible to use a scalpel or the tissue punch proposed by AXIS.

A large round bur can be used to prepare the bone crest.

Implant Site Preparation

Round bur (B1011)



Point drill (B1012)



Mark the implant site using a round bur.
The point drill can also be used at this stage.
1.4 mm round bur and point drill: max. 800 rpm

Ø 2.4 mm Primary Drilling

Pilot drill (B1013)



Drill the implant site to the final depth using the pilot drill.
Pilot drill: max 800 rpm

Parallelism Control

Direction indicator (B1022)



Measure the depth of the site and assess its orientation using the direction indicator.

Ø 2.9 mm Drilling

Drill S (B1014)



Widen the implant site using the S drill (yellow ring).
Drill S: max 550 rpm

Ø 3.4 mm Drilling

Drill M (B1015)



Widen the implant site using the M drill (red ring).
Drill M: max 500 rpm

Depth Control

Depth gauge M
(B1024)



Measure the depth of the site using the M depth gauge (red ring).

Ø 4.0 mm Tapping

Tap M (B1082)



For class I and II bone, tap the site using the tap M (red ring).
Tap M: max 15 rpm and 35 Ncm

Ø 4.5 mm Profile Drilling

Profile drill (B1170)



If desired, the implant can be inserted deeper into the bone using the profile drill.

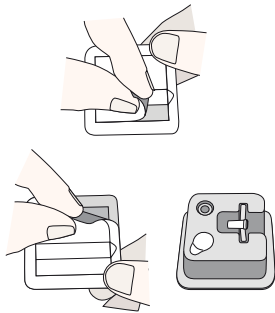


Working depth indicated on the instrumentation are specific for transgingival implant positioning. When using the profile drill, the implant site should be 1.5 mm deeper.

iii. Implant Insertion

Implant Unpacking

Remove the blister from its packaging.



Each AXIS implant has its own article and batch number. To ensure the necessary tracking of products, this information must appear on the patient folder. For this purpose, labels are available on the blister of each implant.

Remove the lid of the blister and deposit the inlay on a sterile surface.

Precautions

The implant should not be placed in the mouth if the packaging is damaged or if the implant was in contact with a non-sterile surface. **In this situation, the product must be replaced. Implant resterilizing is not allowed.**

Packaging and sterilizing images (*Appendix 2*)

Do not use if packing is damaged	
Do not reuse	
Do not resterilize	

3. Hexalobe Implant's Operating Procedure

Gripping and Inserting the Implant

Two types of protocols are available: - using the **torque wrench** (A),
- using a **right angle** (B).

Important

Our Hexalobe implant holder has a mechanical fuse feature that prevents any over-torque application or irregular efforts. In case of misuse, the Hexalobe implant holder may break at the fuse level. In order to complete surgery despite an implant holder rupture, **it is recommended to always have a second Hexalobe implant holder available.**

A. Protocol with the Torque Wrench

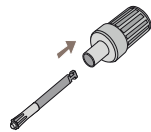
Hexalobe implant holder (B1021)



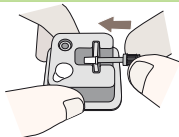
Wrench adapter (C1030)



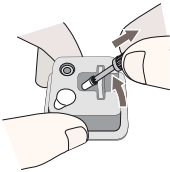
Torque wrench (C1031)



Connect the implant holder to the wrench adapter.



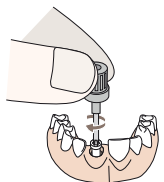
Hold the blister horizontally and connect the implant holder to the implant.



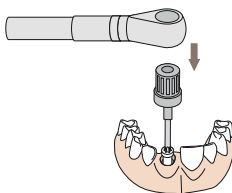
Release the implant from its location by rotating it over its apical end.

Note

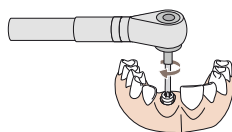
A cavity was created on the inlay to deposit, if necessary, the implant on a sterile surface.



Start inserting the implant manually.



Connect the torque wrench to the adapter.



Screw the implant into the implant site until the end of the thread (see the opposite paragraph concerning *Insertion Depth*).



Always keep the best possible alignment between instruments and implant.

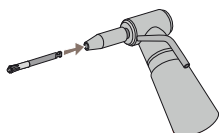
Implants should be screwed to a maximum torque of 35 Ncm.

Note

To avoid any damage to the implant, the implant holder breaks in case of improper use.

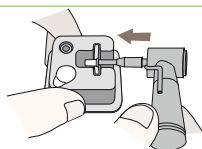
B. Protocol with the right angle

Hexalobe implant holder (B1021)

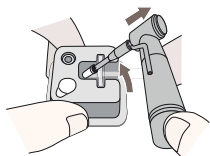


Connect the implant holder to the right angle.
If necessary, use an handpiece extension.

Handpiece extension (C1029)



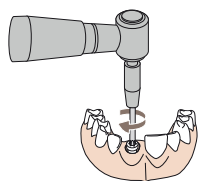
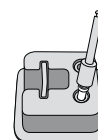
Hold the blister horizontally and connect the implant holder to the implant.



Release the implant from its location by rotating it over its apical end.

Note

A cavity was created on the inlay to deposit, if necessary, the implant on a sterile surface.



Screw the implant into the implant site until the end of the thread (see paragraph concerning *Insertion Depth* below).



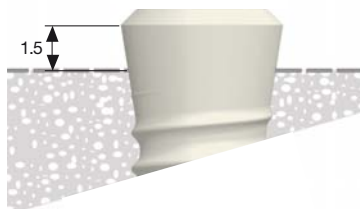
Always keep the best possible alignment between instruments and implant.
Implants should be screwed to a maximum torque of 35 Ncm and a maximum speed of 15 rpm.

Note

To avoid any damage to the implant, the implant holder breaks in case of improper use.

Insertion Depth

AXIS implants are transgingival. The implant's neck should be approximately 1.5 mm above the bone crest.



They can also be inserted deeper into the bone using the profile drill.



Working depth indicated on the instrumentation are specific for transgingival implant positioning. When using the profile drill, the implant site should be 1.5 mm deeper.

3. Hexalobe Implant's Operating Procedure

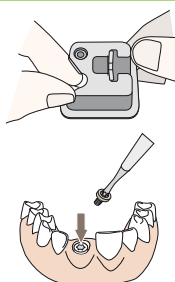
iv. Soft Tissue Management

Several soft tissue management options are proposed: - **Cover screw (A)**,
- **Cover screw (B)**,
- **Temporary abutment (C)**.

A. Cover screw

RA Screwdriver (C1156)

Cover screw (D1145)



A cover screw is provided with each AXIS Hexalobe implant. It is located in the cavity of the blister sealed with a transparent lid.

Remove the lid and take the cover screw with the screwdriver. Suture the gingiva over the cover screw.



In order to avoid failures, the cover screw must be tightened to a maximum torque of 15 Ncm.

Cover screws are partially made out of PEEK which should not be used more than 180 days in the mouth.

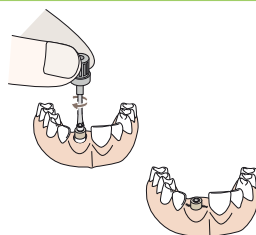
B. Healing abutment

RA Screwdriver (C1158)

Healing abutments
(D1050, D1132)



Prosthetic screw
(D1149)



Depending of the case, gingiva formers are available in 2.5 mm or 4 mm height.

Use the screwdriver to tight the screw. Suture the gingiva around the implant collar



In order to avoid failures, the screw must be tightened to a maximum torque of 15 Ncm.

Gingiva formers are made out of PEEK which should not be used more than 180 days in the mouth.

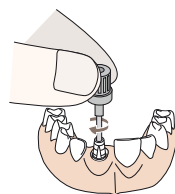
C. Temporary abutment

RA Screwdriver (C1158)

Prosthetic screw
(D1149)



Temporary abutment
(D1131)



A temporary abutment is available. It allows a temporary restoration in aesthetic zone.

Use the screwdriver to tight the screw. Realize directly a temporary crown on the temporary abutment accordingly to the case and the standard method of the clinic.



In order to avoid failures, the screw must be tightened to a maximum torque of 15 Ncm.

Temporary abutments are made of PEEK which should not be used more than 180 days in the mouth.

v. Healing

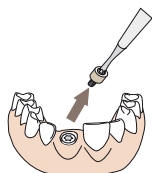
The duration of soft tissue healing and osseointegration of AXIS' implants vary generally from 2 to 4 months. It depends on the general state of health of the patient and the quality of the bone around the implant.

It is possible to use standard means to control the osseointegration.

B. Prosthetic Procedure

i. Impression

RA Screwdriver (C1158)



Exposing the implant connexion

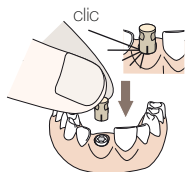
Temporarily remove the soft tissue device.

After exposing the implant connexion, choose either a **clipped transfer** (A) or an **open tray transfer** (B) to take an impression.

A. Clipped transfer

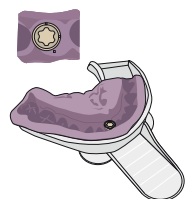
Hexalobe transfer cap

(D1040)



Positioning the transfer cap

Position and lock the hexalobe transfer cap on the implant. The cap will «click» when it is locked.



Taking the impression

Put light impression material around the cap and the implant and heavy impression material in the closed tray. Place the tray in the mouth, let it harden following the manufacturer's recommendations, remove the tray.

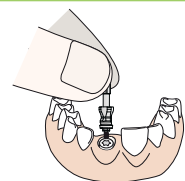
Note

Polyether or rubber polyvinylsiloxane based material are recommended for making quality impressions.

B. Open tray impression

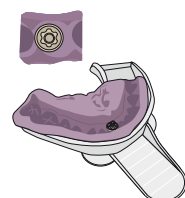
Open tray transfer

(D1152)



Positioning the transfer cap

Position the transfer cap and tight it manually with the provided screw.



Taking the impression

Note

Be sure that a corresponding perforation is made in the tray and that you can access the screw before the material hardens.

Put light impression material around the cap and the implant and heavy impression material in the closed tray. Place the tray in the mouth, let it harden following the manufacturer's recommendations, remove the tray. Loosen the screw to remove the tray.

3. Hexalobe Implant's Operating Procedure

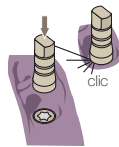
ii. Reconstruction

Making the Model

Two options are available for the realization of the master-model: - **Clipped transfer (A)**,
- **Open tray transfer (B)**.

A. Clipped transfer

Hexalobe analog (D1042)



Setting up the analog implant

Position and lock the analog in the impression tray.
The analog implant will «click» when it is locked.

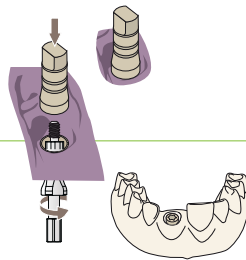


Making the master model

Make the master model following a standard method.

B. Open tray impression

Hexalobe analog (D1042)



Setting up the analog implant

Position the analog in the connexion transfer. Tight it manually.

Making the master model

Make the master model following a standard method.

Plannification

Laboratory abutments

(D1158, D1159, D1160)



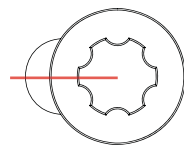
Laboratory screw

(D1084)



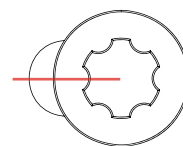
To choose the angulation of the restoration, straight and angulated 15° (version A and B) laboratory abutments are available.

Note on difference between versions A and B abutments



Version A

Angulation facing
the lobe



Version B

Angulation facing
the groove

Making the Crown

Abutments (D1154,

D1155, D1157)



Laboratory screwdriver

(C1028)



Realize the crown following a standard method.

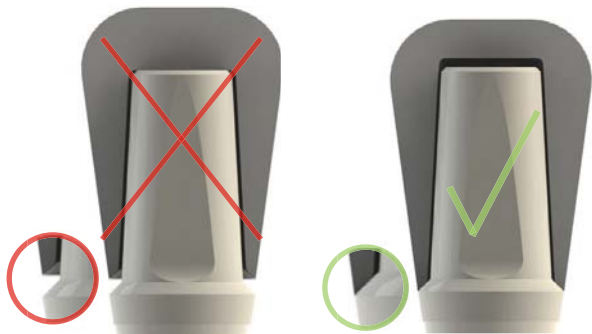
Notes

To maintain the integrity of the master model, it is recommended to manually screw the elements using the AXIS screwdriver (*ref. C1028*). Laboratory screws (*ref. D1084*) are green and are only dedicated for laboratory use. They should not be used by a clinician.

Attention

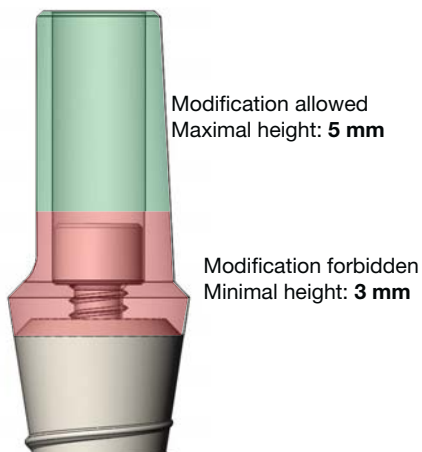
Each implant must replace a single tooth and support a single crown.

Implant-Crown Assembly



To ensure a perfect sealing and an optimal mechanical resistance, the crown must stand on the implant collar.

Modification of the Abutment



If it is necessary, only the green area, highlighted on the left-hand side figure, can be modified.

Please note that only one abutment height is available. Abutments are made out of High performance polymer easily adjustable. Such changes are under the responsibility of the practitioner and the prosthetist.

If the abutment has not been modified, a positioning key is not necessary, the abutment being multi-symmetric.

Scanning

Most of standard scanning techniques can be used with AXIS implants. For further information, please refer to manufacturer's instructions.

3. Hexalobe Implant's Operating Procedure

iii. Rehabilitation

Final Abutment Set Up

Prosthetic screw
(D1149)

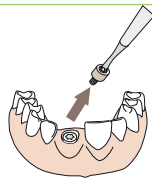


RA Screwdriver (C1158)

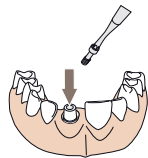


Disinfection

Before rehabilitation, neutral disinfectants (no chlorine, ammonia, or aldehyde) should be used according to manufacturers' recommendations for disinfecting prosthetic parts.



Unscrew the soft tissue management device.



Place the abutment on the implant and lock it with a new screw.

Important

For rehabilitation, only use a new screw.
Laboratory screws are green and are not suitable for implantation.



In order to avoid failures, prosthetic screw must be tightened at a maximum torque of 25 Ncm. Holistic screw must be tightened at a maximum torque of 15 Ncm.

Crown Sealing



Comments

Before sealing the prosthetic part, it is necessary to seal the screw's well with a material like Teflon, gutta-percha or cotton. Do not use resin.

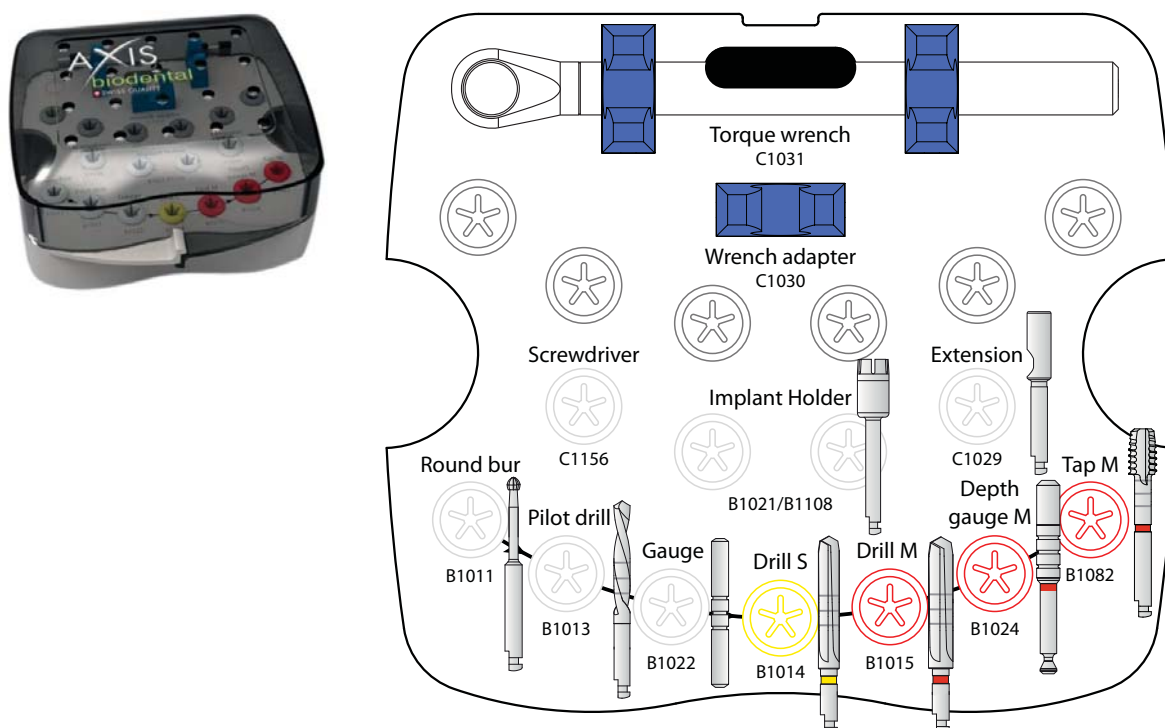
Seal the previously disinfected crown on the abutment. Ideally, use a MDP resin-type adhesive. Please refer to the instructions provided by the manufacturer.

4. Monobloc Implant's Operating Procedure

A. Surgical Procedure

i. Instruments Presentation

A sterilizable implantology kit (ref. B1085), containing all necessary instruments required to place AXIS implants is available.



Attention

All instruments must be sterilized before use.

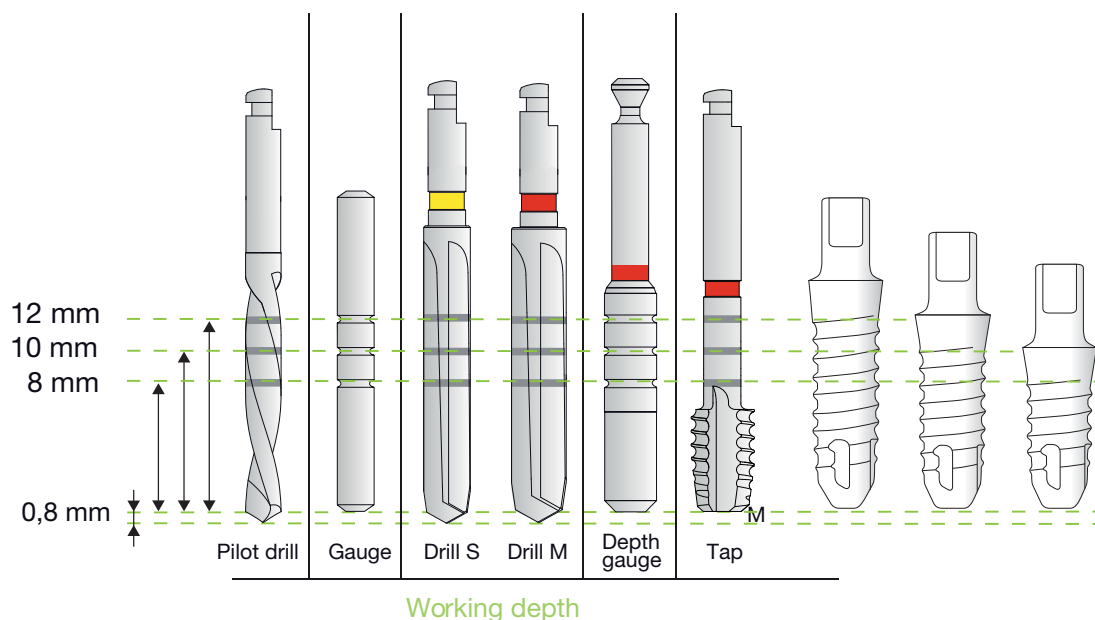
For sterilizing procedures, please refer to Section 6: *Cleaning - Sterilizing - Storage*.

4. Monobloc Implant's Operating Procedure

In addition to the content of the surgical kit, other instruments are available.

Tissue punch (ref. B1010)	
Rofile drill (ref. B1170)	
Point drill (ref. B1012)	
Handpiece extension (ref. C1029)	

Three tick marks indicating the working depth (8, 10 and 12 mm) have been etched on the instruments required for realizing the implant site.



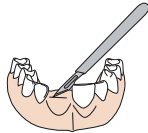
Important

In order to create optimal conditions for the integration of the implant, it is imperative to **respect the recommended speeds** and to apply a **reasonable pressure** during the site preparation. The respect of these rules will prevent over-heating which could slow or prevent the osseointegration of the implant due to **bone necrosis**.

ii. Implant Site Preparation

Osseous Crest Access

Tissue punch (B1010)



For accessing the bone, it is possible to use a scalpel or the tissue punch proposed by AXIS.

A large round bur can be used to prepare the bone crest.

Implant Site Preparation

Round bur (B1011)



Point drill (B1012)



Mark the implant site using a round bur.

The point drill can also be used at this stage.

1.4 mm round bur and point drill: max. 800 rpm

Ø 2.4 mm Primary Drilling

Pilot drill (B1013)



Drill the implant site to the final depth using the pilot drill.

Pilot drill: max 800 rpm

Parallelism Control

Direction indicator (B1022)



Measure the depth of the site and assess its orientation using the direction indicator.

Ø 2.9 mm Drilling

Drill S (B1014)



Widen the implant site using the S drill (yellow ring).

Drill S: max 550 rpm

Ø 3.4 mm Drilling

Drill M (B1015)



Widen the implant site using the M drill (red ring).

Drill M: max 500 rpm

Depth Control

Depth gauge M

(B1024)



Measure the depth of the site using the M depth gauge (red ring).

Ø 4.0 mm Tapping

Tap M (B1082)



For class I and II bone, tap the site using the tap M (red ring).

Tap M: max 15 rpm and 35 Ncm

Ø 4.5 mm Profile Drilling

Profile drill (B1170)



If desired, the implant can be inserted deeper into the bone using the profile drill.



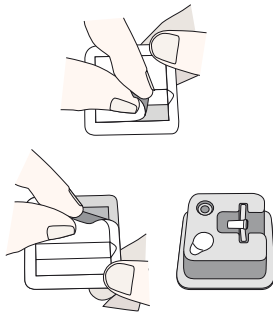
Working depth indicated on the instrumentation are specific for transgingival implant positioning. When using the profile drill, the implant site should be 1.5 mm deeper.

4. Monobloc Implant's Operating Procedure

iii. Implant Insertion

Implant Unpacking

Remove the blister from its packaging.



Each AXIS implant has its own article and batch number. To ensure the necessary tracking of products, this information must appear on the patient folder. For this purpose, labels are available on the blister of each implant.

Remove the lid of the blister and deposit the inlay on a sterile surface.

Precautions

The implant should not be placed in the mouth if the packaging is damaged or if the implant was in contact with a non-sterile surface. **n this situation, the product must be replaced. Implant resterilizing is not allowed.**

Packaging and sterilizing images (*Appendix 2*)

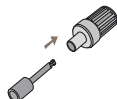
Do not use if the packaging is damaged	
Do not reuse	
Do not resterilize	

Gripping and Inserting the Implant

Two types of protocols are available: - using the **torque wrench** (A),
- using a **right angle** (B).

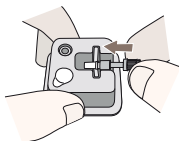
A. Protocol with the Torque Wrench

Monobloc
implant-holder (B1108)



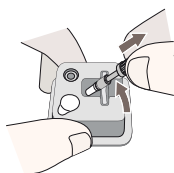
Connect the implant holder to the wrench adapter.

Wrench adapter (C1030)



Hold the blister horizontally and connect the implant holder to the implant.

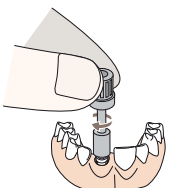
Torque wrench (C1031)



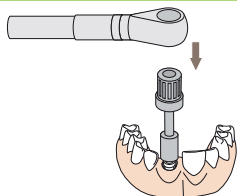
Release the implant from its location by rotating it over its apical end.

Note

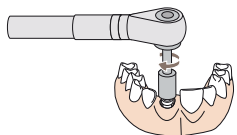
A cavity was created on the inlay to deposit, if necessary, the implant on a sterile surface.



Start inserting the implant manually.



Connect the torque wrench to the adapter.



Screw the implant into the implant site until the end of the thread (see the opposite paragraph concerning *Insertion Depth*).



Always keep the best possible alignment between instruments and implants.
Implants should be screwed to a maximum torque of 35 Ncm.



Remove the instruments and suture the gum.

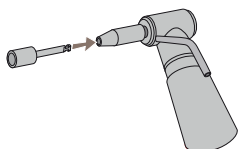
4. Monobloc Implant's Operating Procedure

B. Protocol with the right angle

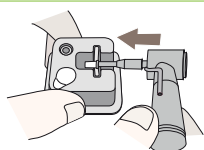
Monobloc
implant-holder (B1108)



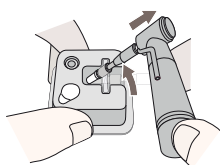
Handpiece extension
(C1029)



Connect the implant holder to the right angle.
If necessary, use an handpiece extension.



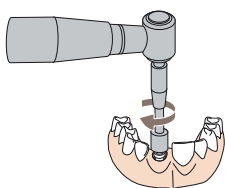
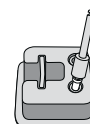
Hold the blister horizontally and connect the implant holder to the implant.



Release the implant from its location by rotating it over its apical end.

Note

A cavity was created on the inlay to deposit, if necessary, the implant with the implant holder on a sterile surface.



Screw the implant into the implant site until the end of the thread (see paragraph concerning *Insertion Depth* below).



Always keep the best possible alignment between instruments and implants

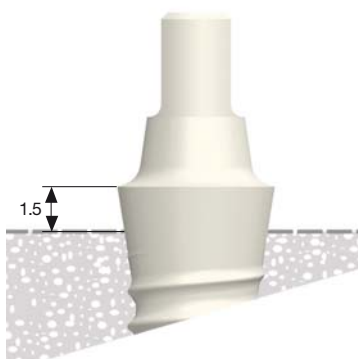
Implants should be screwed to a maximum torque of 35 Ncm and a maximum speed of 15 rpm.



Remove the instruments and suture the gum.

Insertion Depth

Monobloc AXIS implants are transgingival. The implant's neck should be approximately 1.5 mm above the bone crest.



They can also be inserted deeper into the bone using the profile drill.



Working depth indicated on the instrumentation are specific for transgingival implant positioning. When using the profile drill, the implant site should be 1.5 mm deeper.

iv. Healing

To avoid loading the implant during osseointegration, AXIS biodental recommends achieving temporary rehabilitation in under-occlusion mode.

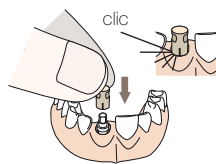
The duration of soft tissue healing and osseointegration of AXIS' implants vary generally from 2 to 4 months. It depends on the general state of health of the patient and the quality of the bone around the implant.

It is possible to use standard means for the control of osseointegration.

B. Prosthetic Procedure

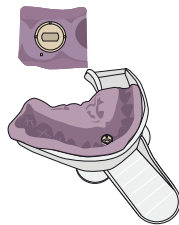
i. Impression

Monobloc transfer cap
(D1036)



Positioning the transfer cap

Position and lock the transfer cap on the implant. The cap will «click» when it is locked.



Taking the impression

Put light impression material around the cap and the implant and heavy impression material in the closed tray.

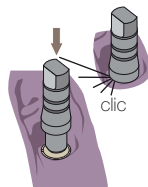
Place the tray in the mouth, let it harden following the manufacturer's recommendations, then remove the tray.

Note

Polyether or rubber polyvinylsiloxane based material are recommended for making quality impressions.

ii. Reconstruction

Monobloc analog
(D1037)



Setting up the analog implant

Position and lock the analog implant in the impression tray. The analog implant will «click» when it is locked.



Making the master model

Make the master model following a standard method.

4. Monobloc Implant's Operating Procedure

Making the Crown

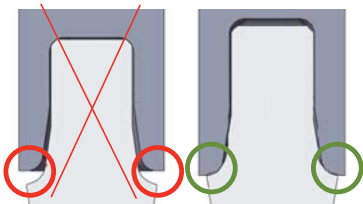


Make the crown following a standard method.
It is recommended to sandblast the abutment in order to increase the adhesion of the crown.

Attention

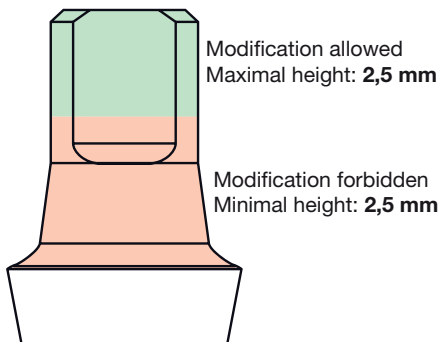
Each implant must replace a single teeth and support a single crown.

Implant-Crown Assembly



For mechanical reasons and to ensure the sealing, the crown must stands on the implant chamfer.

Modification of the Abutment



AXIS recommends not modifying the abutment. However, if it is necessary, only the green area, highlighted on the left-hand side figure, can be modified.

The modification of the abutment must be made with a fine diamond bur under irrigation and with moderate pressure in order to avoid heating the material and generating micro-cracks.
Such changes are the responsibility of the practitioner and the prosthetist.

Scanning

Most of standard scanning techniques can be used with AXIS implants.
For further information, please refer to manufacturer's instructions.

iii. Rehabilitation

Crown Sealing



Comments

Neutral disinfectants (no chlorine, ammonia, or aldehyde) should be used according to manufacturers' recommendations for disinfecting prosthetic parts.

Seal the previously disinfected crown on the abutment. Many adhesives for the bonding of zirconium oxide are available on the market. Ideally, sandblast the abutment and use a MDP resin-type adhesive. Please refer to the instructions provided by the manufacturer.

5. Implantation Follow-up

To prevent any problems, regular clinical follow-up is recommended. Ideally, the tracking should be realized by the clinician in charge of the implantation.

The follow-up, proposed here-under, must be adapted accordingly to the clinical history of each patient.

After implantation: Inform the patient on the post-operative procedure in case of any problem. Draw the patient's attention to the importance of a good dental hygiene and its influence on the implantation success.

After rehabilitation: 6 months after rehabilitation, a follow-up visit will ensure the perfect behavior of the implant. Inform the patient about the importance of communicating all problems encountered (discomfort, ache...).

Long term: It is recommended to realize an annual X-ray. More controls could be necessary for high risk patient, suffering from parodontitis for example.

A good follow-up, ensured by a dentist and/or a dental hygienist, as well as a good dental hygiene, are necessary conditions for the long-term success of an implantation.

As for natural teeth, implants are exposed to influences of the buccal cavity: dental plaque, tartar, bacteria... In case of insufficient care, complications (inflammation, bleeding...) can lead to the loss of the implant.

1

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6-7

Appendix

6. Cleaning - Sterilizing - Storage

All devices entering into direct contact with the patient should be **sterilized** prior to use

Exceptions:

- Products clearly identified as sterile (implant with the cover screw).
- Abutments and crowns must be decontaminated prior to use with a low or intermediate EPA-registered hospital disinfectant. Strictly follow manufacturer's instructions.

Non-sterile components should be removed from their original packaging prior to sterilizing. Cleaning and sterilizing of these components before their first use is under the responsibility of the clinician.

Sterilizing Steps

Decontamination: Put the instruments in a disinfectant solution immediately after use. Do not let the contaminated instruments dry.

Cleaning and disinfection: Disassemble the instruments that can be taken apart (torque wrench). Group components according to their composing materials in order to avoid electrolysis and corrosion.

Submerge them in a disinfectant:

- Cleaning solutions with high chlorine content or oxalic acid are inappropriate for the cleaning of stainless steel instruments (risk of corrosion)
- Alkaline products with a pH higher than 9 are inappropriate for cleaning tools made of anodized aluminum (risk of deteriorating the surface).

Cleaning can be done manually or mechanically (by ultrasound).

Be careful to dry the parts with clean compressed air.

Inspection: Check for cleanliness and proper function of instruments and components.

Reassemble the disassembled instruments. Replace damaged instruments.

To ensure optimal performance, the rotating equipment should not be used more than 10 times.

Packaging: The instruments can be packaged individually or inserted in their dedicated location in the implantology kit, which will be then packed before sterilizing.

Sterilizing: Chemical and hot air sterilizing are inappropriate. Sterilizing by saturated steam is recommended using the following parameters: 134 °C during 18 minutes. The recommended drying time should be between 20 to 60 minutes.

For components sterilized at dental practice, the validity depends on various factors such as material used for packing, storage conditions... refer to standard procedure of the dental practice.

For sterile delivered components, an expiration date is indicated on the labelling (see *Appendix 2*).

No component must be used beyond the expiration date.

Storage: Store the bags in a clean and dry place.

7. Technical Support

What is to be done in case of problem or if you have any question?

In case of problems or if you have any questions, please contact your local representative (agent, distributor, ...).

Breaking of the Prosthetic Screw

Wrench adapter (C1030)



Prosthetic screw extraction kit (C1122):
Point driver (1A)



Pointer (1B)



Extraction drill driver (2A)



Extraction drill (2B)



Helicoidal extractor (3)



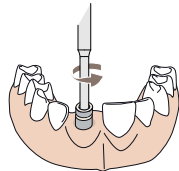
If the prosthetic screw breaks, a part may get stuck inside the implant.

A Prosthetic screw extraction kit is dedicated to the removal of the rest of the screw without damaging the implant. This kit is composed of a point drill, a drill, an extractor and two guide rings. It is available under reference C1122 for titanium screw and under C1166 for holistic screw.

Note: Before anything else, be sure to clean the implant connection and remove any fragments.

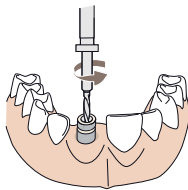
Realization of a drilling point

Insert the point driver (1A) into the implant connection and insert the pointer (1B) with no speed until it is in contact with the screw. Put the driver in counterclockwise rotation at 800 rpm during approximately 10 seconds while exercising a moderate pressure. Remove the driver and the pointer.



Drilling the screw

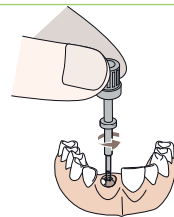
Insert the extraction drill driver (2A) into the implant and introduce the extraction drill (2B) with no speed until it is in contact with the screw. Put the drill in counterclockwise rotation at 1'000 rpm, drill up to the stop and remove the instrument always in rotation. Remove the driver.



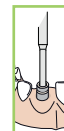
Note: it is possible that the screw comes already out at this stage

Screw extraction

Assemble the helicoidal extractor (3) and the adapter. Place the extractor in the hole previously realized in the screw. Then turn manually counterclockwise by exercising a moderate pressure to bind the extractor in the hole.



Be sure to use all these instruments counterclockwise. Always keep the best alignment between instruments and implant, even with a guide ring.



Breaking of the Implant

Trephine Ø4.0mm (B1144)



Trephine Ø4.5mm (B1143)



For removing an osseointegrated implant, use the trephine.






When using the trephine, apply moderate pressure and do not exceed 800 rpm in order to prevent bone overheating.








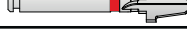


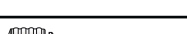
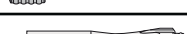

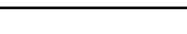
All items that have been removed are recommended to be placed in a buffer solution containing 10% Neutral Buffered Formalin for proper preservation.

To perform tests and analysis required, please contact your local representative.

Appendix 1 - Rotation Speeds & Torques

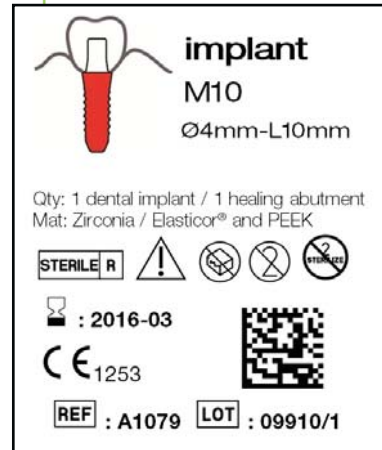


Device	Designation	Reference	Maximal speed (rpm)	Maximal torque (Ncm)
	Implant	A1078-1080	15	35
	Monobloc implant	A1074-1076	15	35
	Prosthetic screw	D1047	/	25
	Holistic prosthetic screw	D1165	/	15
	Laboratory screw	D1050	/	manually

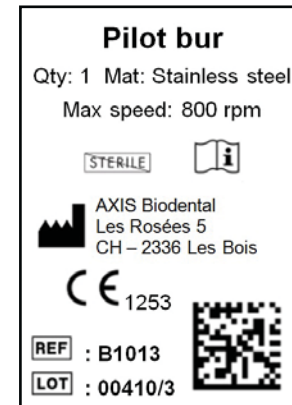
Instrument	Designation	Reference	Maximal speed (rpm)
	Tissue punch	B1010	800
	Round bur	B1011	800
	Point drill	B1012	800
	Pilot bur	B1013	800
	Drill S	B1014	550
	Drill M	B1015	500
	Tap M	B1082	15
	Profile drill	B1170	300
	Trepine Ø4	B1144	800
	Trepine Ø4.5	B1143	800
	RA screwdriver	C1156	/
	Laboratory screwdriver	C1028	/
	Hexalobe holder	B1021	/
	Monobloc holder	B1108	/

Appendix 2 - Labelling Explanations

Implant Label



Instrument Label



Symbol Explanation

CE marking	
Manufacturer	
Expiration date	
Batch number	
Reference	
Non-sterile	
Sterile	
Caution - Read the instructions for use	
Information - Read the instructions for use	
Do not resterilize	
Do not reuse	
Do not use if the packaging is damaged	
Keep away from direct sunlight	
Maximal speed (clockwise or anti-clockwise rotation)	
Maximal torque (clockwise rotation only)	



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